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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/696,174	Applicant(s) JAYARAMAN, SWAMINATHAN	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 52,56-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (5282823). Fig. 2 shows a stent perform with a metallic core **2** and an outer sheath **8** disposed about the contact surface and the ends of the core wire. Schwartz discloses the wire is made of metal, col. 4, lines 7,8,26,27. Schwartz also discloses the sheath encapsulates the wire, col. 4, lines 21,22,47. Schwartz additionally discloses the sheath can include a therapeutic agent, col. 7, lines 2-4. Schwartz et al. also disclose that the sheath is a polymer and can be bioabsorbable, col. 4, lines 14-16. Additionally two therapeutic agents could be used, col. 7, lines 45-48. The therapeutic material can be applied on the outer surface of the sheath or film, col. 7, lines 14-16 and a release mechanism (microcapsules) can be used, lines 17-22.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. '823 in view of Mitchell et al. (5288711). Schwartz et al. is explained supra. However, Schwartz et al. fail to disclose the therapeutic agents include rapamycin. Mitchell et al. teach that rapamycin is used on a stent (col. 7, lines 16-18) because it reduces intimal smooth muscle cell hyperplasia and reduces restenosis, col.

5, lines 3-8,17-25. It would have been obvious to one of ordinary skill in the art to incorporate rapamycin with the vascular device as taught by Mitchell et al. with the vascular implant of Schwartz et al. such that it aids in controlling the vascular response of hyperplasia that is primary cause of restenosis.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. '823 in view of Stinson (5980564). Schwartz et al. is explained supra. However, Schwartz et al. fail to disclose the sheath or film is contains pores. Stinson teaches (Fig. 2c) pores 42 are used on a biodegradable stent material (col. 10, lines 66-67) because it enhances the degradation of the material. It would have been obvious to one of ordinary skill in the art to incorporate pores with the stent as taught by Stinson into the sheath or film of Schwartz et al. stent such that it can accelerate degradation and speed up delivery of therapeutic agents.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. '823 in view of Liprie et al. (6491662). Schwartz et al. is explained supra. However, Schwartz fails to disclose the core is made of shape memory alloy. Liprie et al. teach that a core is made of shape memory alloy to strengthen the vascular device, col. 2, lines 36-43. It would have been obvious to one of ordinary skill in the art to substitute metal materials and use a SMA as taught by Liprie with the device of Schwartz such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp.

Claims 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. '284 in view of Sukhatme (2005/261283). Schwartz et al. is explained

supra. However, Schwartz fails to disclose the method of treating a vascular disease and the use of rapamycin with the drug imatinib mesylate in combination. Sukhatme teaches a method of treating a vascular disease by determining a pathologic process resulting from a disease and selecting therapeutic agents to treat the disease, paragraph 16. Sukhatme also teaches that rapamycin and imatinib mesylate can be used to effectively treat hyperplasia, paragraphs 117,151,164. Sukhatme also teaches that the devices are implanted and the patient is monitored, paragraph 260. Additionally it should be noted that a plurality of wires in stents are well known in the art and used in interlaced form. It would have been obvious to one of ordinary skill in the art to utilize the teachings of Sukhatme of assessing a vascular disease and combining drugs such as rapamycin with the drug imatinib mesylate to be used in the stent of Schwartz et al. to treat vascular disease.

Response to Arguments

Applicant's arguments with respect to new claims 52-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER
Brian E. Pellegrino